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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,368	12/20/1999	PETER KAMP HANSEN	4324.224-US	2312
25908	7590	03/03/2006	EXAMINER	
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			RAO, MANJUNATH N	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/467,368	Applicant(s) HANSEN ET AL.	
	Examiner Manjunath N. Rao, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 72-95 are currently pending and are present for examination.

Applicants' arguments filed on 1-6-06, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 85 recites the phrase “consists of a sequence of amino acids 32-225 of SEQ ID NO:2”. It is not clear whether said xylanase consists of the full length of amino acids 32-225 or “a sequence” of the same, i.e., any amino acid fragment of amino acids 32-225. Examiner suggests deletion of “of a sequence” (underlined above for emphasis) in the above phrase.

Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 86 recites the phrase “xylanase comprises an amino acid sequence of SEQ ID NO:2”. It is not clear whether said xylanase comprises the full length of SEQ ID NO:2 or “an amino acid sequence” of the same, i.e., any amino acid fragment of SEQ ID NO:2.

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Examiner suggests deletion of “an” (underlined above for emphasis) and replacing it with “the” in the above phrase.

Claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 87 recites the phrase “xylanase consists of an amino acid sequence of SEQ ID NO:2”. It is not clear whether said xylanase comprises the full length of SEQ ID NO:2 or “an amino acid sequence” of the same, i.e., any amino acid fragment of SEQ ID NO:2. Examiner suggests deletion of “an” (underlined above for emphasis) and replacing it with “the” in the above phrase.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 72-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lischnig et al. (Biotechnology letters, 1993, Vol. 15(4):411-414) or Gomes et al. (Appl. Microbiol. Biotechnol., 1993, Vol. 39:700-707) and Haarasilta et al. (US 5,314,692, 5-24-1994), Hazlewood et al. (WO 93/25693, 12-23-1993).

Claims 72-95 of the instant application are drawn to an animal feed comprising a xylanase enzyme isolated from *Humicola lanuginosa* (Syn., *Thermomyces lanuginosus*) with

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characteristics as disclosed in claim 72 and a method of improving the growth of an animal by feeding said animal feed.

Lischnig et al. or Gomes et al. teach the isolation and characterization of the xylanase enzyme from *Humicola lanuginosa*. Applicants also acknowledge (See page 1, line 28-33) such a teaching in the above references. However, the references do not teach the use of said enzyme for supplementing an animal feed or an animal feed comprising said enzyme.

The use of xylanases for supplementation of animal feeds has been known in the art for quite some time. The references of Hazlewood et al. and Haarasilta et al. teach the extensive use of xylanase enzymes in food and feed industry (see the entire reference of Hazlewood et al., specifically pages 20-23). Specifically Hazlewood et al. teach that chicks when fed feeds supplemented with xylanase improve in their weight gain. The reference teaches that the effects of undigested pentosans --which have been implicated for poor nutrient uptake and sticky droppings-- can be overcome by the use of feed supplemented with xylanase.

Therefore combining the teachings of the above references, it would have been obvious to one skilled in the art to use the knowledge existing in the field of enzyme purification, and recombinant techniques at the time the application was filed, to purify the thermostable xylanase taught by Lischnig et al. or Gomes et al. to homogeneity and use it for making an animal feed comprising said enzyme or make recombinant DNA or isolate polynucleotides that hybridize to said recombinant DNA under the highly stringent conditions and isolate the encoded xylanase and use it for making an animal feed as claimed in claims 72-95. While the references may not teach the testing of the enzyme for residual activity at the temperatures claimed in the instant application, they all teach that the enzyme is thermostable. Furthermore, since the enzyme in the

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references has been isolated from the very same microorganism as that in the instant application, Examiner takes the position that the enzyme in the reference and the enzyme claimed in the instant application are one and the same and the thermostable characteristics and residual activity characteristics are all inherent features of the enzyme. One of ordinary skill in the art would have been motivated to do so as the xylanases taught in the above references are thermostable and therefore withstand the higher temperatures that may have to be used during the process of making, storing and transporting the feed. One of ordinary skill in the art would have a reasonable expectation of success since the art is rich in teachings regarding use of xylanase enzyme in the field of food and feed industry, and specifically Hazelwood et al. demonstrate such a use. Therefore Lischnig et al. or Gomes et al. in combination with Hazlewood et al. or Haarasilta et al. render claims 72-95 *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office action, applicants have again traversed the above rejection basically arguing that none of the cited references teach or suggest the use of thermostable xylanases in animal feed composition or that there would be any advantage to using a thermostable xylanase over a thermolabile xylanase in animal feed. Applicants also provide a publication of Dr. Pettersson and reiterate the point of unexpected results and the statistical significance of the results of experiments supporting unexpected results. While the findings of Dr. Pettersson, are acceptable to the Examiner, the labeling of said results as unexpected for all feeds and in all animals is unacceptable. According to the M.P.E.P. it is the responsibility of the primary examiner to personally review and decide whether affidavits or declarations submitted under 37 CFR 1.132 for the purpose of traversing grounds of rejection are responsive to the rejection and present sufficient facts to overcome the rejection. This rule sets forth the

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general policy of the Office consistently followed for a long period of time of receiving affidavit evidence traversing rejections or objections. All affidavits or declarations presented which do not fall within or under other specific rules are to be treated or considered as falling under this rule. Examiner notes that the publication of Dr. Pettersson et al. is limited to studying the effect of *T.lanuginosus* xylanase on a single feed component, wheat, and is restricted to chicken fed said wheat and in comparison to only two other xylanases. The study is also limited to the use of a single *T.lanuginosus* enzyme and its comparison to only two other xylanases. However, the claims are drawn to animal feed comprising any component, not limited to wheat, as well as not limited to feeding only chicken. On similar lines, the enzyme claimed to be comprised in the claimed animal feed is not limited to a single enzyme i.e., xylanase comprising SEQ ID NO:2 but those that have an amino acid sequence 95% identical to SEQ ID NO:2 and those xylanases encoded by polynucleotides which can hybridize to nucleotides 31-705 of SEQ ID NO:1 under a specific set of stringent conditions. Therefore, while the evidence provided by Dr. Pettersson can be considered as unexpected for SEQ ID NO:2, such consideration cannot be given to all variants and mutants of SEQ ID NO:2 as claimed because such unexpected results have not been demonstrated for those variants and mutants or with feeds comprising more than wheat as a feed component and fed to a representative number of different animals. Therefore, while applicant's arguments are persuasive for an animal feed comprising wheat as the main component, comprising SEQ ID NO:2 as the xylanase enzyme, wherein said feed is made for feeding chicks or poultry, their arguments in support for animal feed comprising any component, comprising a genus of xylanases including variants and mutants of SEQ ID NO:2, for feeding any or all animals, as claimed are not persuasive. Hence the above rejection is maintained.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,245,546 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same xylanase enzyme encoded by the same polynucleotide (nucleotides 31-705 of SEQ ID NO:1) and a premix and a process of making animal feed comprising the above xylanase enzyme.

In response to the above rejection in the previous Office action, applicants have responded that they will submit a Terminal Disclaimer upon the indication of allowable subject matter. Examiner maintains the rejection for reasons of record.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-

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0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura

Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao, Ph.D.

Primary Examiner

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February 23, 2006